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09/719,415	04/04/2001	Heine Hansen	12012/121412	8314

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EXAMINER
STOCK JR, GORDON J

ART UNIT	PAPER NUMBER
2877	

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/719,415	Applicant(s) HANSEN, HEINE
	Examiner Gordon J Stock	Art Unit 2877

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-37 and 40-42 is/are rejected.

7)☒ Claim(s) 38-39 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 04 April 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Objections

1. **Claim 21** is objected to for the following: the phrase, "the memory," lacks antecedent basis. Correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 15, 35, and 42** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding **claim 42**, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding **claims 15 and 35**, the phrase "optionally" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. **Claims 1-4, 7, 13-17, 21-24, 27, 33-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scharlack (5,828,445)**.

As for **claims 1 and 21**, Scharlack discloses a method for measuring and reporting co-oximeter quality control results of a spectrophotometer, particularly co-oximeter, comprising determining an absorption spectrum of a fluid quality control sample with a significant absorbance peak with a steep flank and a reference absorption spectrum of a reference quality control sample stored (col. 2, lines 5-20; col. 3, lines 45-67; col. 4, lines 34-55; col. 5, lines 1-25; Figs. 1 and 4). As for the wavelength shift it may be predetermined (col. 6, lines 1-15). And the error spectrum is derived from a reference and measured absorbance at each wavelength (col. 5, lines 15-25). Therefore, it would be obvious that the wavelength shift is determined for the error spectrum comprises the difference between the measured and estimated spectra at each wavelength.

As for **claims 2 and 22**, Scharlack discloses everything as above (see **claims 1 and 21**). In addition, Scharlack discloses the error spectrum is determined from an absorption spectrum and a predetermined mathematical parameter (col. 4, lines 35-65; col. 5, lines 1-25).

As for **claims 3-4, 23-24**, Scharlack discloses everything as above (see **claims 2 and 22**). In addition, Scharlack discloses the mathematical parameter is a coefficient vector (col. 5, lines 25-60). As for the vector fulfilling the equation whereas the wavelength shift equals the vector times the absorbance spectrum, Scharlack discloses the equations 6a and 6b and 3 (col. 5, lines 11, 47, and 52). It would be obvious to one skilled in the art at the time the invention was made that wavelength shift equals the vector times the absorbance spectrum for the substitution of

equation 3 into equation 6a gives the error spectrum equaling a coefficient vector times the absorbance spectrum.

As for **claims 7 and 27**, Scharlack discloses everything as above (see **claims 1 and 21**). He is silent concerning normalization, but discloses that values are made nominal are set to those values observed in normal human blood (col. 3, lines 1-5) and well-known mathematical techniques of fitting spectra can be used (col. 5, lines 1-10). Therefore, it will be obvious to one skilled in the art that the wavelength shifts is determined after normalization of the determined spectrum with an estimate of the dye, for values are set to those values in normal human blood, and normalization is a well-known mathematical technique.

As for **claims 13 and 33**, Scharlack discloses a co-oximeter (col. 3, lines 45-55).

As for **claims 14 and 34**, Scharlack discloses the wavelength ranges at least 500 to 640 nm (see Figs. 1-4).

As for **claims 15 and 35**, Scharlack discloses determining estimated errors in blood parameters (col. 6, lines 1-65).

As for **claims 16-17, 36-37**, Scharlack discloses determining estimated errors in blood parameter values reported by the spectrophotometer caused by a difference between c_{est} and c_{qc}, and between q_{est} and q_{qc} (col. 4, lines 35-65; col. 5,1-25; col. 6, lines 1-15)

7. **Claims 5-6, 8, 18-20, 25, 26, and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scharlack (5,828,445)** in view of **Maggard (WO 94/08225)**.

As for **claims 5-6, 25-26**, Scharlack discloses everything as above (see **claims 4 and 24**). In addition, Scharlack discloses the reference spectrum is determined on a calibrated spectrophotometer (col. 4, lines 34-50) and that known mathematical techniques of fitting are

used (col. 5, lines 1-10). Maggard in a spectroscopic instrument calibration discloses that Taylor series and linear combinations of derivatives are used in the calibration of spectra (pages 14-17). It would be obvious to one skilled in the art that Taylor series and first derivatives are used to determine reference and therefore to determine the vectors, for Taylor series and linear combinations of derivatives of spectra are used in the calibration and fitting of spectra.

As for **claims 8 and 28**, Scharlack discloses everything as above (see **claims 1 and 21**). In addition, Scharlack discloses errors are adjusted to new values (col. 6, lines 1-15); and the reference spectrum is determined on a calibrated spectrophotometer (col. 4, lines 34-50) and that known mathematical techniques of fitting are used (col. 5, lines 1-10). Also Maggard discloses that in calibrating spectra a wavelength shift, absorbance shift, is derived (pages 14-17). Therefore, it would be obvious to one skilled in the art that an assigned wavelength shift for the quality control sample is compared to the wavelength shift, for a wavelength shift of the reference spectra is derived in fitting and calibrating the reference spectrum.

As for **claims 18-20**, Scharlack discloses that a first concentration and second concentration levels are used in deriving parameters (Figs. 2 and 4). And that vectors and matrices, linear combinations of vectors, are derived (col. 5, lines 5-65). And the reference spectrum is determined on a calibrated spectrophotometer (col. 4, lines 34-50) and that known mathematical techniques of fitting are used (col. 5, lines 1-10). Therefore, it would be obvious to one skilled in the art that calibrated vectors are determined for the reference spectrum is taken on a calibrated spectrophotometer and fit to a spectrum using known mathematical techniques. As for the calibrated vectors being linear combinations of spectra and derivative of spectra, Maggard teaches that in a calibrating of spectra, linear combinations of derivatives are used (pages 14-17).

Therefore, it would be obvious to one skilled in the art that the set of vectors are linear combinations of component spectra and derivatives of spectra, for in calibrating linear combinations of derivatives are used and matrices are used that are combinations of spectral component vectors.

8. **Claims 9-12 and 29-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scharlack (5,828,445)** in view of **Campbell et al. (EPO 0 132 399)**.

As for **claims 9-12 and 29-32**, Scharlack discloses everything as above (see **claims 1 and 21**). And discloses "n" components (col. 4, lines 25-30). Campbell in cooximetry quality control reagents teaches that the quality control may contain more than one dye that mimics the spectral response of blood at a plurality of wavelengths (page 6, lines 5-10). Therefore, it would be obvious to have a quality control sample comprise more than one dye component in order to mimic blood over a plurality of wavelengths.

As for the particular parameters, Scharlack discloses similar parameters using different variables (col. 4; equations 1 and 2; col. 5; equations 3, 4, and 5). And the estimated concentration of the dye as a linear combination may be seen in the use of vectors and matrices in the estimation of absorbance spectrum and the errors in the measured concentration of blood components (col. 5, liens 5-55) and the apparent concentrations are derived (col. 6, lines 1-55).

As for c_{est} and c_{qc}, they will be compared by the error spectrum and the relation of concentration to the absorbance spectrum (equations 4 and 5).

As for Q_{qc} and Q_{est} equaling s_2 divided by s_1, fractional component concentrations are determined (equations 7-10) and as for comparing them, they will be compared by the error spectrum and the relation of concentrations to the absorbance spectrum (equations 4, 5, 7-10).

9. **Claims 40-41** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scharlack (5,828,445)** in view of **Shaw (3,638,640)** and in view of **Shepherd et al. (6,262,798)**.

As for **claims 40-41**, Scharlack discloses everything as above. The spectrometer detects wavelengths at least in the range 500-640 (Figs. 1-4). And discloses compensating for errors derived (col. 6, lines 1-15). The derived spectrum in memory was taken from a calibrated spectrophotometer (col. 4, lines 35-65). He is silent concerning a spectral lamp and photodiodes that have their current ratioed. However, Shaw in an oximeter discloses that at least photodiodes are used to detect a specific wavelength and the currents ratioed to determine concentrations (col. 2, lines 35-50; col. 3, lines 15-45). Therefore, it would be obvious to have at least photodiodes in order to ratio the currents from the specific wavelengths detected to determine a component concentration. In addition, Shepherd in a method of a spectrophotometric method for unaltered blood teaches using a neon lamp as light source (col. 8, lines 55-67). Therefore, it would be obvious to one skilled in the art at the time to have the light source for the spectrophotometric analysis comprise a neon lamp, for neon lamps are utilized as light sources in the spectral analysis of blood.

10. **Claim 42** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scharlack (5,828,445)** in view of **Shaw (3,638,640)** and in view of **Shepherd et al. (6,262,798)** and further in view of **Carim et al. (5,553,615)**

As for **claim 42**, Scharlack in view of Shaw and Shepherd discloses everything as above (see **claim 41**). They are silent concerning temperature activation. Carim in an apparatus for prediction of hematocrit teaches temperature activation of a light source in order to prevent unnecessary heating of the sample being investigated (col. 14, lines 20-67; col. 15, lines 1-35).

Therefore, it would be obvious to one skilled in the art at the time the invention was made to have the light source temperature activated in order to prevent unnecessary heating of the sample being investigated.

Allowable Subject Matter

11. **Claims 38-39** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As to **claim 38**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a spectrophotometer for the determination of a concentration of a component y of a sample wherein the processor is further adapted to calculating the particular concentration of the interfering component and the particular modified absorbance spectrum if the particular concentration of the interfering component is greater than a predetermined threshold value, in combination with the rest of the limitations of **claims 38-39.**

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent 5,933,792 to Andersen et al.

U.S. Patent 5,243,546 to Maggard

Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

1) Contain either a statement "DRAFT" or "PROPOSED AMENDMENT" on the fax cover sheet; and

2) Should be unsigned by the attorney or agent.

This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is: **(703) 308-7722**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon J. Stock whose telephone number is (703) 305-4787. The examiner can normally be reached on Monday-Friday, 10:00 a.m. - 6:30 p.m.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

gs
September 3, 2003

Zandra V. Smith
Primary Examiner
Art Unit 2877